UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

NOVO NORDISK A/S AND NOVO NORDISK INC., Plaintiffs, v. RLT WEIGHT LOSS LLC, Defendant.	Case No. 24-3753

COMPLAINT

Plaintiffs Novo Nordisk A/S ("NNAS") and Novo Nordisk Inc. ("NNI") (collectively, "Plaintiffs" or "Novo Nordisk"), by and through their attorneys, Covington & Burling LLP, file their complaint against RLT Weight Loss LLC ("Defendant") for false advertising and unfair competition, and seek injunctive and other relief. Plaintiffs allege as follows, on actual knowledge with respect to themselves and their own acts, and on information and belief as to all other matters.

INTRODUCTION

1. Novo Nordisk is a healthcare company with a 100-year history of innovation in developing medicines to treat serious chronic diseases like diabetes and obesity.

2. The development of semaglutide is an example of Novo Nordisk's commitment to innovation for people living with chronic diseases. Semaglutide is the foundational molecule that serves as the primary ingredient for Novo Nordisk's three prescription-only medicines approved by the Food and Drug Administration ("FDA"): Ozempic® (semaglutide) injection and Rybelsus® (semaglutide) tablets for adults with type 2 diabetes and Wegovy® (semaglutide) injection for chronic weight management.

3. Novo Nordisk is the only company in the United States with FDA-approved medicines containing semaglutide. Novo Nordisk is also the only company authorized to identify its

FDA-approved semaglutide medicines using the trademarks Ozempic®, Wegovy®, and Rybelsus®. The FDA has not approved any generic versions of semaglutide. To the contrary, the FDA has sent warning letters to companies which claimed that their Unapproved Products have the "same active ingredient as Ozempic, Rybelsus, and Wegovy," noting that Ozempic and Wegovy are currently the only "two injectable semaglutide products FDA-approved for the U.S. market."[1]

4. This is an action brought pursuant to the Lanham Act, 15 U.S.C. §§ 1051 et seq., related state laws, and the common law arising out of Defendant's infringement of Plaintiffs' rights in their Ozempic® and Wegovy® marks and Defendant's acts of false advertising and unfair competition.

5. Defendant uses Novo Nordisk's Ozempic®, Wegovy®, and Rybelsus® marks to market and sell to patients compounded drug products that purport to contain semaglutide. Despite such compounded drug products having not been evaluated by the FDA for their safety, effectiveness, or quality, Defendant falsely and misleadingly represents to patients that its products are FDA-approved or the same as, or equivalent to, Novo Nordisk's FDA-approved semaglutide medicines.

6. Defendant's conduct is likely to confuse and deceive patients into mistakenly believing that they are purchasing authentic Novo Nordisk medicines or medicines that have been evaluated by the FDA, studied in clinical trials, and deemed safe and effective.

THE PARTIES

7. Plaintiff NNAS is a corporation organized and existing under the laws of the Kingdom of Denmark and has its principal place of business in Bagsværd, Denmark.

[1] FDA – Warning Letter to Ozempen.com, MARCS-CMS 684435 — JUNE 24, 2024, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/ozempencom-684435-06242024#:~:text=WARNING%20LETTER&text=As%20discussed%20below%2C%20FDA%20has,new%20drugs%20and%20misbranded%20drugs.

8. Plaintiff NNI is a corporation organized and existing under the laws of Delaware and has its principal place of business in Plainsboro, New Jersey.

9. NNI promotes, offers, and/or sells Novo Nordisk's Ozempic®, Wegovy®, and Rybelsus® medicines throughout the United States, including in this District. NNAS has granted to NNI exclusive rights to market, advertise, promote, offer for sale and sell Ozempic®, Wegovy®, and Rybelsus® medicines in the United States.

10. Defendant RLT Weight Loss LLC is a Pennsylvania Limited Liability Company with a registered business address at 301 Oxford Valley Road, Suite 801B, Yardley, Pennsylvania 19607, in this judicial district. Defendant sells and promotes compounded drug products that purport to contain semaglutide.

JURISDICTION AND VENUE

11. The Court has subject matter jurisdiction over the Lanham Act causes of action pleaded herein pursuant to 35 U.S.C. § 1121 and 28 U.S.C. § 1338(a). The Court has supplemental jurisdiction over the state and common law causes of action pleaded herein pursuant to 28 U.S.C. § 1338(b).

12. Venue is proper in this District pursuant to 28 U.S.C. § 1391 because Defendant operates in this District, manufactures and/or sells its compounded drug products that purport to contain semaglutide in this District, and otherwise conducts business in this District. Defendant is subject to personal jurisdiction in this District.

NOVO NORDISK'S FDA-APPROVED SEMAGLUTIDE MEDICINES AND OZEMPIC®, WEGOVY®, AND RYBELSUS® TRADEMARKS

13. Plaintiffs use the trademarks "Ozempic," "Wegovy," and "Rybelsus" to identify and promote the FDA-approved Ozempic®, Wegovy®, and Rybelsus® medicines. The Ozempic®, Wegovy®, and Rybelsus® medicines are sold and marketed in the United States by NNAS's indirect, wholly-owned subsidiary, NNI.

14. The Ozempic® medicine is indicated for adults with type 2 diabetes to improve blood sugar (glucose), along with diet and exercise. Ozempic® also lowers the risk of major cardiovascular events such as stroke, heart attack, or death in adults with type 2 diabetes and known heart disease.

15. The Wegovy® medicine is indicated to reduce excess body weight and maintain weight reduction long term in adults and children aged ≥ 12 years with obesity, and some adults with overweight and weight-related medical problems, along with a reduced calorie diet and increased physical activity. The Wegovy® medicine is also indicated, with a reduced calorie diet and increased physical activity, to reduce the risk of major adverse cardiovascular events such as "cardiovascular" death, heart attack, or stroke in adults with known heart disease and with either obesity or overweight.

16. The Rybelsus® medicine is indicated for adults with type 2 diabetes to improve blood sugar (glucose), along with diet and exercise.

17. The Ozempic®, Wegovy®, and Rybelsus® medicines have been extensively studied in clinical trials and are FDA-approved.

18. Each of the Ozempic®, Wegovy®, and Rybelsus® medicines has a unique safety and efficacy profile which is detailed in its respective product label.

19. The Ozempic®, Wegovy®, and Rybelsus® medicines are prescription-only medicines that should only be prescribed in direct consultation with, and under the supervision of, a licensed healthcare professional.

20. Novo Nordisk first adopted and used the Ozempic® mark at least as early as 2017, and has used it continuously since that time.

21. The Ozempic® trademark is inherently distinctive.

22. Novo Nordisk has promoted, advertised, and marketed its prescription-only medicine using the Ozempic® mark in many different channels, directed to physicians, other health care professionals, and patients, including on the websites ozempic.com and novonordisk-us.com. As a result of its use of the Ozempic® mark, NNAS owns valuable common law rights in and to the Ozempic® mark.

23. Novo Nordisk first adopted and used the Wegovy® mark at least as early as 2021, and has used it continuously since that time.

24. The Wegovy® trademark is inherently distinctive.

25. Novo Nordisk has promoted, advertised, and marketed its prescription-only medicine using the Wegovy® mark in many different channels, directed to physicians, other health care professionals, and patients, including on the websites wegovy.com and novonordisk-us.com. As a result of its use of the Wegovy® mark, NNAS owns valuable common law rights in and to the Wegovy® mark.

26. Novo Nordisk first adopted and used the Rybelsus® mark at least as early as 2018 and has used it continuously since that time.

27. The Rybelsus® trademark is inherently distinctive.

28. Novo Nordisk has promoted, advertised, and marketed its prescription-only medicine using the Rybelsus® mark in many different channels, directed to physicians, other health care professionals, and patients, including on the websites rybelsus.com and novonordisk-us.com. As a result of its use of the Rybelsus® mark, NNAS owns valuable common law rights in and to the Rybelsus® mark.

29. As a result of Novo Nordisk's long use, promotion, and advertising of the Ozempic®, Wegovy®, and Rybelsus® trademarks and medicines, the Ozempic®, Wegovy®, and

Rybelsus® marks are exclusively associated with Plaintiffs, serve to identify genuine Novo Nordisk medicines, and are valuable assets of Novo Nordisk.

30. As a result of Novo Nordisk's long use, promotion, and advertising of the Ozempic®, Wegovy®, and Rybelsus® trademarks and medicines, the Ozempic®, Wegovy®, and Rybelsus® trademarks are well-known, strong, and famous marks, and became such prior to any of the acts of Defendant complained of herein.

DEFENDANT'S SALE OF UNAPPROVED COMPOUNDED DRUGS

31. Novo Nordisk has not authorized Defendant to use its marks, has not provided Defendant with Novo Nordisk's FDA-approved semaglutide medicines, and does not sell the bulk semaglutide in Novo Nordisk's FDA-approved semaglutide medicines to any compounding pharmacies from which it may be sourcing its Unapproved Compounded Drugs.

32. Defendant markets and sells to patients Unapproved Compounded Drugs that purport to contain semaglutide and that are not approved by the FDA.

33. On information and belief, the Unapproved Compounded Drugs sold by Defendant are made by compounding pharmacies, which deliver them either directly to patients or to Defendant for administration or dispensing to patients.

34. The FDA defines compounding as a "practice in which a licensed pharmacist, a licensed physician, or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient."[2]

[2] Human Drug Compounding, https://www.fda.gov/drugs/guidance-compliance-regulatory-information/human-drug-compounding.

35. According to the FDA, "[c]ompounded drugs are not FDA-approved. This means that FDA does not review these drugs to evaluate their safety, effectiveness, or quality before they reach patients."[3]

36. The FDA has further stated that compounded drugs "do not have the same safety, quality, and effectiveness assurances as approved drugs. Unnecessary use of compounded drugs unnecessarily exposes patients to potentially serious health risks."[4] As the FDA has explained, "[c]ompounded drugs pose a higher risk to patients than FDA-approved drugs because compounded drugs do not undergo FDA premarket review for safety, quality or effectiveness. Compounded drugs should only be used for patients whose medical needs cannot be met by an available FDA-approved drug.[5]

37. The FDA has received reports of adverse events, some requiring hospitalization, related to overdoses from dosing errors associated with compounded "semaglutide" products.[6] In several instances, patients mistakenly administered five to 20 times more than the intended dose of compounded "semaglutide." The FDA believes the containers and packaging used by compounders, including multidose vials and prefilled syringes, the varying product concentrations, and the instructions accompanying the compounded drug contribute to the potential medical errors. A previous publication from the Journal of the American Pharmacists Association also highlighted administration errors where patients accidentally self-administered doses of compounded "semaglutide" up to 10 times greater than the intended amount.[7]

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[3] Compounding Laws and Policies, https://www.fda.gov/drugs/human-drug-compounding/compounding-laws-and-policies.
[4] Compounding and the FDA: Questions and Answers, https://www.fda.gov/drugs/human-drug-compounding/compounding-and-fda-questions-and-answers.
[5] FDA Alerts Health Care Providers, Compounders and Patients of Dosing Errors Associated with Compounded Injectable Semaglutide Products, https://www.fda.gov/drugs/human-drug-compounding/fda-alerts-health-care-providers-compounders-and-patients-dosing-errors-associated-compounded?utm_medium=email&utm_source=govdelivery.
[6] FDA Alerts Health Care Providers, Compounders and Patients of Dosing Errors Associated with Compounded Injectable Semaglutide Products, https://www.fda.gov/drugs/human-drug-compounding/fda-alerts-health-care-providers-compounders-and-patients-dosing-errors-associated-compounded.
[7] Joseph E. Lambson et al, Administration Errors of Compounded Semaglutide Reported to a Poison Control Center—

38. FDA has issued guidance on "Medications Containing Semaglutide Marketed for Type 2 Diabetes or Weight Loss," which provides that: (1) "compounded drugs are not FDA-approved or evaluated for safety and effectiveness"; and (2) "FDA has received adverse event reports after patients used compounded semaglutide. Patients should not use a compounded drug if an approved drug is available to treat a patient. Patients and health care professionals should understand that the agency does not review compounded versions of these drugs for safety, effectiveness, or quality."[8]

DEFENDANT'S FALSE ADVERTISING IN CONNECTION WITH ITS SALE OF UNAPPROVED COMPOUNDED DRUGS

39. Despite the foregoing, and well after NNAS's first use of its Ozempic®, Wegovy®, and Rybelsus® marks, Defendant has used Novo Nordisk's Ozempic®, Wegovy®, and Rybelsus® trademarks to market and sell Unapproved Compounded Drugs purporting to contain "semaglutide" that are not Ozempic®, Wegovy®, nor Rybelsus®, and has made false and misleading representations to patients regarding the nature of its Unapproved Compounded Drugs.

40. Defendant has, for example, falsely advertised its Unapproved Compounded Drugs by making statements that describe Ozempic®, Wegovy®, and Rybelsus® but that are false or misleading when in reference to Defendant's Unapproved Compounded Drugs.

41. Defendant has claimed or implied that its Unapproved Compounded Drugs have been approved by the FDA or have been reviewed by the FDA for safety, effectiveness, and quality.

Case Series, 63 J. Am. Pharmacists Assc'n 5 (2023), available at https://www.japha.org/article/S1544-3191(23)00231-5/abstract.

[8] Medications Containing Semaglutide Marketed for Type 2 Diabetes or Weight Loss, https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/medications-containing-semaglutide-marketed-type-2-diabetes-or-weight-loss.

42. Defendant has claimed or implied that its Unapproved Compounded Drugs contain the same semaglutide that the FDA evaluated in the context of reviewing and approving Novo Nordisk's new drug applications for Wegovy®, Ozempic®, and Rybelsus®.

43. Defendant has claimed or implied that its Unapproved Compounded Drugs have been subjected to clinical studies and trials, or have otherwise achieved certain therapeutic outcomes attributable to Wegovy®, Ozempic®, and Rybelsus®.

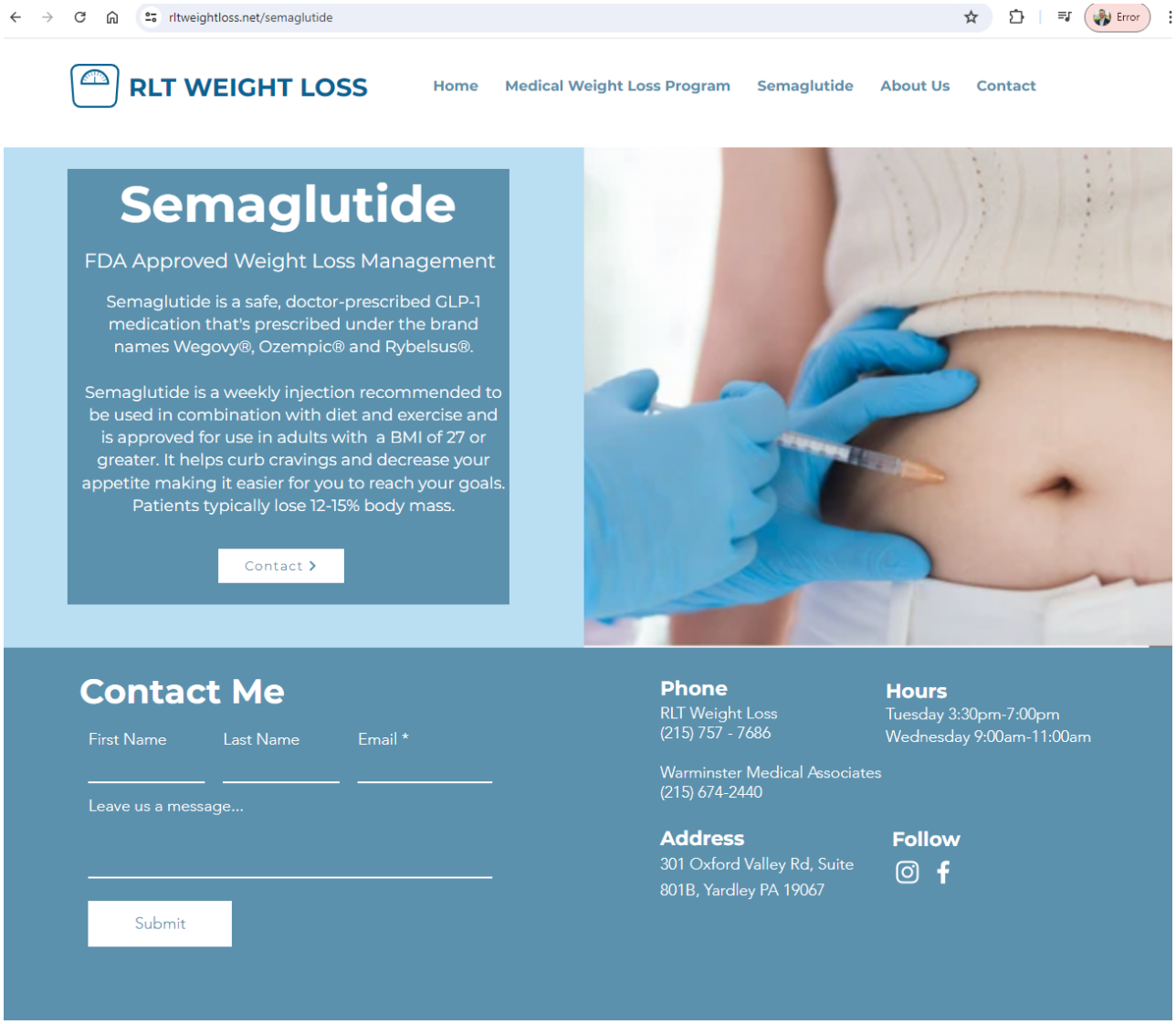
44. On information and belief, Defendant has engaged in these unlawful practices to attract customers and generate revenues and profits.

45. Defendant's prominent and misleading use of the Ozempic®, Wegovy®, and Rybelsus® marks is likely to cause patients to believe falsely that they are actually purchasing genuine Wegovy®, Ozempic®, and Rybelsus® medicines and that Defendant's services are provided, licensed, sponsored, authorized, or approved by Novo Nordisk.

46. Defendant's use of the Ozempic®, Wegovy®, and Rybelsus® marks is without the permission, consent or authorization of Novo Nordisk. Defendant has no right to use, and Defendant knows that it has no right to use, the Ozempic®, Wegovy®, and Rybelsus® marks in connection with Defendant's Unapproved Compounded Drugs

47. Novo Nordisk has no control over the nature, quality, or efficacy of the products sold by Defendant, including the Unapproved Compounded Drugs.

48. Defendant promotes its Unapproved Compounded Drugs by offering a "Medical Weight Loss Program" including on its website and social media pages as reflected below:



49. Defendant misleadingly claims that "Semaglutide is a safe, doctor-prescribed GLP-1 medication that's prescribed under the brand names Wegovy®, Ozempic®, and Rybelsus®," indicating and implying that its Unapproved Compounded Drugs are equivalent to Plaintiffs' FDA-approved semaglutide medicines.

50. Defendant similarly misleadingly claims that Semaglutide is "the new FDA approved treatment for weight management," further falsely conveying that its Unapproved

Compounded Drugs are equivalent to Plaintiffs' FDA-approved semaglutide medicines:

51. As depicted above, Defendant further claims that its Unapproved Compounded Drug product will enable customers to "lose 12-15% body mass." On information and belief, this claim is misleading and unsupported because it is based on studies of Plaintiffs' FDA-approved semaglutide medicines, not studies of Defendant's Unapproved Compounded Drugs.

52. Defendant's false and misleading marketing is also likely to expose patients to unnecessary risks. Patients who mistakenly believe Defendant to be offering Novo Nordisk's FDA-approved medicines, or equivalent thereto, are unlikely to understand the unique risks associated with, or the lack of clinical trials or testing establishing the safety and effectiveness of, Defendant's Unapproved Compounded Drugs.[9]

[9] *See, e.g.*, Dozens Say They Lost Eyesight After Routine Surgery Using Compounded Pharmacy Drugs, WFAA, https://www.wfaa.com/article/news/do-not-publish-yet/287-5f002ed3-e110-4063-9959-a2e5f54b5097 (reporting mistaken belief of patient taking a compounded drug that "every pill you take, every shot you take is tested.").

53. On information and belief, unless enjoined by this Court, Defendant's unauthorized use of the Ozempic®, Wegovy®, and Rybelsus® trademarks will continue to cause confusion, mistake, and deception.

FIRST CAUSE OF ACTION

Defendant's False and Misleading Advertising and Promotion in Violation of 15 U.S.C. § 1125(a)(1)(B)

54. Plaintiffs reallege and incorporate by reference each of the allegations in the preceding paragraphs of this Complaint as though fully set forth here.

55. Defendant's practices, as described in this Complaint, constitute unfair competition and false advertising in violation of Section 43(a)(1)(B) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B).

56. Defendant has violated the Lanham Act by using false or misleading descriptions of fact and false or misleading representations of fact in its commercial advertising or promotion that misrepresent the nature, characteristics, and/or qualities of Defendant's business practices and products, as set forth above.

57. Defendant has also engaged in other false or misleading advertising and promotion intended to assure patients that Defendant's practices are lawful. On information and belief, Defendant provides patients who purchase Defendant's Unapproved Compounded Drugs (or whom Defendant is trying to persuade to purchase its drugs) information that makes several false or misleading statements, including those described herein.

58. The above-described acts of Defendant, if not enjoined by this Court, are likely to deceive members of the general public.

59. The above-described acts of Defendant have irreparably harmed and, if not enjoined, will continue to irreparably harm Plaintiffs.

60. The above-described acts of Defendant have irreparably harmed and, if not enjoined, will continue to irreparably harm the interest of the public in being free from confusion, mistake, and deception.

61. By reason of Defendant's acts as alleged above, Plaintiffs have suffered and will continue to suffer injuries, including injury to Plaintiffs' business reputation. However, Plaintiffs' remedies at law are not adequate to compensate for all the injuries inflicted by Defendant. Accordingly, Plaintiffs are entitled to entry of preliminary and permanent injunctive relief requiring Defendant to cease its false and misleading advertising and promotion and unfair competitive practices.

62. Because the above-described acts of Defendant are willful, Plaintiffs are entitled to disgorgement of Defendant's profits (enhanced at the Court's discretion), treble damages, and costs under 15 U.S.C. § 1117.

63. This is an exceptional case, making Plaintiffs eligible for an award of attorneys' fees under 15 U.S.C. § 1117.

SECOND CAUSE OF ACTION

Unfair Competition in Violation of the Common Law

64. Plaintiffs reallege and incorporate by reference each of the allegations in the preceding paragraphs of this Complaint as though fully set forth here.

65. The above-described acts of Defendant constitute common law unfair competition.

66. The above-described acts of Defendant unfairly and wrongfully exploit Plaintiffs' trademark, goodwill, and reputation.

67. By reason of the above-described acts of Defendant, Plaintiffs have suffered damage to the goodwill associated with the Ozempic®, Wegovy®, and Rybelsus® trademarks.

68. The above-described acts of Defendant have irreparably harmed and, if not enjoined, will continue to irreparably harm Plaintiffs and the Ozempic®, Wegovy®, and Rybelsus® trademarks.

69. The above-described acts of Defendant have irreparably harmed and, if not enjoined, will continue to irreparably harm the interest of the public in being free from confusion, mistake, and deception.

70. By reason of Defendant's acts, Plaintiffs' remedies at law are not adequate to compensate for the injuries inflicted by Defendant. Accordingly, the Court should enter preliminary and injunctive relief, in addition to awarding disgorgement of Defendant's profits (enhanced at the Court's discretion) and corrective advertising costs to NNAS.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs request judgment against Defendant as follows:

1. That the Court enter a judgment against Defendant that Defendant has:

   a. Engaged in false and misleading advertising and promotion, in violation of 15 U.S.C. § 1125(a);

   b. Engaged in unfair competition under the common law of Pennsylvania.

2. That each of the above acts was willful.

3. That the Court preliminarily and permanently enjoin and restrain Defendant and its agents, servants, employees, successors, and assigns, and all other persons acting in concert with or in conspiracy with or affiliated with Defendant, from:

   a. using the Ozempic®, Wegovy®, and Rybelsus® marks in any manner that is likely to cause confusion or mistake, to deceive, or otherwise infringe Novo Nordisk's rights in the Ozempic®, Wegovy®, and Rybelsus® marks in any way, or in connection with the advertising, marketing, sale, or promotion of any Unapproved Compounded Drugs; and,

b. advertising, stating, or suggesting that any Unapproved Compounded Drugs, including but not limited to any Unapproved Compounded Drugs that either are available, directly or indirectly, from or through Defendant or the use of which or access to which is facilitated by, or with the involvement of, Defendant:

   i. are, or contain, genuine or authentic Novo Nordisk Ozempic®, Wegovy®, and Rybelsus® medicines;

   ii. are sponsored by or associated with Novo Nordisk;

   iii. are approved by the FDA; have been reviewed by the FDA for safety, effectiveness, or quality; or have been demonstrated to the FDA to be safe or effective for their intended use;

   iv. achieve or have been shown or proven to achieve certain therapeutic results, effects, or outcomes, including but not limited to by relying on or making reference to clinical trial results for Novo Nordisk's medicines;

   v. achieve or have been shown or proven to achieve therapeutic results, effects, or outcomes similar or identical to Novo Nordisk's medicines and/or are interchangeable with or equivalent to genuine Novo Nordisk medicines;

   vi. are associated or connected in any way with Novo Nordisk or Novo Nordisk's medicines; or

   vii. contain any ingredient (including but not limited to semaglutide) that is supplied by Novo Nordisk, is approved by the FDA, or is the same as any ingredient in any Novo Nordisk medicine.

c. engaging in any unfair competition with Plaintiffs; and/or

d. engaging in any deceptive acts or practices.

4. That the Court require Defendant to disclose conspicuously and prominently in any public-facing materials for any Unapproved Compounded Drugs, including but not limited to all advertising, marketing, and promotional materials, that: (a) the Unapproved Compounded Drugs are compounded drugs that have not been approved by the FDA; have not been reviewed by the FDA for safety, effectiveness, or quality; and have not been demonstrated to the FDA to be safe or effective for their intended use; (b) the processes by which the compounded drugs are manufactured have not been reviewed by the FDA; and (c) FDA-approved medicines containing semaglutide are available.

5. That Plaintiffs be awarded monetary relief in the form of disgorgement of Defendant's profits for Defendant's false advertising, and unfair competition.

6. That the Court award disgorgement of Defendant's profits resulting from Defendant's unfair competition to Plaintiffs.

7. That Defendant be ordered to account for and disgorge to Plaintiffs all amounts by which Defendant has been unjustly enriched by reason of Defendant's unlawful actions.

8. That Plaintiffs be awarded punitive damages by reason of Defendant's willful unlawful actions.

9. For pre-judgment and post-judgment interest on all damages.

10. That the Court award Plaintiffs their reasonable attorneys' fees pursuant to 15 U.S.C. § 1117 and any other applicable provision of law.

11. That the Court award Plaintiffs the costs of suit incurred herein.

12. For such other or further relief as the Court may deem just and proper.

August 2, 2024

Respectfully submitted,

/s/ Raymond M. Williams

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